

## II. REMARKS

Claims 21-24 and 26-40 are pending in this application. Claims 33 to 35 have been cancelled without prejudice or disclaimer. Claims 21, 22, 23, 26, 30, 31, 32 and 36 have been amended in a sincere effort to place the application in condition for allowance or in better form for appeal. The amendments to and cancellation of claims are not intended to be a dedication to the public of the subject of the claims as previously presented. Applicants reserve the right to file the same or similar claims pursuant to 35 U.S.C. § 120. The amendments to the claims were not made earlier as it was maintained that the claims as earlier presented patentable subject matter. The amendments to the claims do not raise an issue of new matter and entry of the amendments are respectfully requested.

Following entry of the amendments, claims 21 to 24, 26 to 32 and 36 to 40 as amended, are presently under examination.

### Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 21-24, 26-29, and 36-40 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the grounds for rejection were:

“Claim 21 is indefinite because it recites a step of isolating nucleic acid from a sample, but then the claim requires adding a set of oligonucleotide primers to the sample. It is unclear how, and why, if the nucleic acids have been removed from the sample, one would add oligonucleotides to the sample. Amending the claim to recite “adding a set of oligonucleotide primer pairs to the isolated nucleic acid” would obviate this rejection. All of the claims that depend from claim 21 are indefinite for this reason as well.

Claim 21 is further indefinite over the recitation “...at least five oligonucleotide primer pairs, wherein at least one primer pair is capable of specifically amplifying a DNA sequence to produce an amplified product of a virulence factor gene characteristic of each one of...” because it is not clear if the claim is requiring that one of

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the primer pairs must be able to amplify for all of the recited sequences OR if there must be one primer pair in the set that is able to amplify a virulence factor/toxin gene characteristic for each of the five types of *E. coli*. For the purposes of examination with regard to the prior art, the later interpretation was used. All of the claims that depend from claim 21 are indefinite for this reason as well. Claim 36 is indefinite for the use of similar language to describe the primer pairs.

In claim 24, the phrase "said PCR amplification process" lacks proper antecedent basis because neither claim 24 nor claim 21 previously recite a PCR amplification process."

In response to the rejections under 35 U.S.C. § 112, second paragraph, the claims have been amended as suggested by the Office and in an sincere effort to place the case in condition for allowance. With respect to the rejection of claim 24, Applicants note that claim 21 has been amended to remove the phrase "PCR amplification process" thereby removing the grounds for rejection. In view of these amendments, reconsideration and withdrawal of the grounds for rejection are respectfully requested.

#### **Rejections Under 35 U.S.C. § 103**

Claims 21, 22, 24, 26-31 and 33-40, remain rejected under 35 U.S.C. § 103 for the reasons of record, and therefore will not be repeated herein. However, the Office stated that claims 23 and 32 are free of the prior art. Specifically, the Office stated that:

"[c]laims [23 and 32] require a primer pair that hybridizes to the inv-plasmid of EIEC, and in particular require that the primer pair consists of instant SEQ ID NO: 9 and instant SEQ ID NO: 10. This primer pair is free of the prior art because the prior art does not teach or suggest a primer SEQ ID NO: 10 that would be useful for the specific detection of the inv-plasmid of enteroinvasive *E. coli*. The prior art teaches that SEQ ID NO: 10 is found within the *Shigella flexneri* virulence plasmid (see sequence search result appended below) but does not teach or suggest that this sequence would be useful as a primer for the specific detection of EIEC.

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Thus, for at least this reason, claims 23 and 32 are free of the prior art."

"Claims 23 and 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims."

Without conceding the correctness of the Office's position and in a sincere effort to place the case in condition for allowance, the claims have been amended to recited primer pairs 9 and 10 in the independent claims. Alternatively claims 33-35 have been canceled without prejudice to Applicants' right to file the same or similar claims in a continuation application. In view of the amendments to the claims, reconsideration and withdrawal of the rejections of the claims is respectfully requested. An early Notice of Allowance is earnestly requested.

### III. CONCLUSION

Withdrawal of the pending rejections and reconsideration of the amended claims are respectfully requested, and a notice of allowance is earnestly solicited. Should a telephone interview be of assistance in advancing the subject application, the Office is invited to telephone the undersigned at the number provided below.

Respectfully submitted,

Dated: *May 27, 2003*

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